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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/463,733	06/12/2000	CHARLES ZUKER	02307E-085110US	6739

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EXAMINER	
MYERS, CARLA J	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 09/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/463,733	ZUKER, CHARLES	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-13,15,17,19,20,22,24 and 28-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 5-13, 15, 17, 19, 20, 22, 24 and 28-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to the amendment filed August 16, 2006. Applicant's arguments have been fully considered but are not persuasive to overcome all grounds of rejection. All rejections not reiterated herein are hereby withdrawn. This action is made final.

Claims 1, 5-13, 15, 17, 19, 20, 22, 24, and 28-31 are pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5-13, 15, 17, 19, 20, 22, 24, and 28-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

The specification as originally filed does not appear to provide basis for the amendment to the claims to recite a method of screening for modulators of RDGC GPCR phosphatase activity wherein the method includes providing a second sample containing a mutant rhodopsin lacking the last 18 amino acids at the cytoplasmic terminus, exposing the second sample to a test compound, detecting RDGC GPCR

phosphatase activity in the second sample and comparing the level of RDGC GPCR phosphatase activity of the second sample with a first sample.

In the response filed December 12, 2005, Applicants point to original claims 14, 23 and 32 and to page 44 of the specification as providing support for this amendment.

However, original claims 14, 23 and 32, refer to methods of screening for modulators of RDGC GPCR phosphatase activity wherein the assays include providing a second sample containing a **mutant RDGC phosphatase**. These claims do not provide support for the concept of performing the screening assay using a **mutant rhodopsin**.

The specification at page 44 does disclose a mutant rhodopsin protein in which the COOH-terminal 18 amino acids have been deleted (i.e., Rh1Δ356). The specification (pages 43-44) also teaches an assay in which "RDGC was analyzed biochemically, physiologically, and genetically to determine its activity as a GPCR phosphatase." In these assays, transgenic flies expressing the truncated rhodopsin were analyzed, as were flies expressing wildtype rhodopsin. The specification reports that "(t)he truncated receptor was expressed in near normal amounts and the cells displayed normal light response. Rhodopsin was not hyperphosphorylated in Rh1Δ356 flies."

However, the specification does not disclose the use of the truncated rhodopsin mutant in methods of screening for modulators of RDGC phosphatase activity wherein phosphatase activity is compared in samples containing wildtype rhodopsin and samples containing the truncated rhodopsin. Regarding in vitro and in vivo assays for

modulators of RDGC phosphatase, the specification (e.g., page 22) teaches that the results obtained with rhodopsin and a test compound are compared to "control samples or animals without the test compound." There is no disclosure of using a control sample which contains the test compound and truncated rhodopsin. Accordingly, the specification as originally filed does not appear to set forth the concept of comparing the results obtained with samples containing wildtype rhodopsin to samples containing mutant rhodopsin lacking the last 18 amino acids at the cytoplasmic terminus, to thereby identify modulators of RDGC GPCR phosphatase activity.

Response to arguments:

In the response, Applicants state that the previous Office action indicates that "although mutant rhodopsin is disclosed in the application, there is no support for using a mutant rhodopsin in the screening assays of the invention." Applicants point to pages 25, 32, 35 and 44 as teaching that rhodopsin can be used as a GPCR, that the GPCRs used in the assay may be a mutant GPCR and that RH1delta356 is a mutated rhodopsin in which the C-terminal 18 amino acids have been deleted.

Applicant's arguments have been fully considered but are not persuasive. Applicants characterization of the basis of the rejection is not correct. The rejection is based on the finding that the specification as originally filed does not appear to provide support for the concept of methods of screening for modulators of RDGC phosphatase activity wherein phosphatase activity is compared in samples containing (wildtype) rhodopsin and samples containing the truncated rhodopsin. The specification teaches screening methods in which the results obtained with a test sample are compared to

those obtained with a control sample or animal that does not receive the test compound (see, e.g., page 22). It is also agreed that the specification provides basis for the concept of screening for modulators of RDGC GPCR phosphatase activity in which a mutant rhodopsin is used as a substrate for RDGC phosphatase. In the case of the mutant rhodopsin lacking the C-terminal 18 amino acids, this mutant rhodopsin is missing the residues which become phosphorylated and thereby the mutant rhodopsin is not hyperphosphorylated. However, the specification does not teach the concept set forth in the present claims of performing screening methods in which the results obtained in a sample containing the truncated rhodopsin are compared to results obtained in a first sample containing rhodopsin, and based upon this comparison, detecting RDGC GPCR phosphatase activity in order to identify a modulator of RDGC GPCR phosphatase activity.

The following is a new ground of rejection necessitated by applicant's amendments to the claims:

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-13, 15, 17, 19, 20, 22 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9-13 and 22 are indefinite over the recitation of "the sample" because this phrase lacks proper antecedent basis. While the claims previously refer to a "first sample" and a "second sample," the claims do not previously refer more generically to

"a sample." Accordingly, it is unclear as to whether "the sample" is intended to refer to the first sample, the second sample or both the first and second sample.

Similarly, claim 31 is indefinite over the recitation of "the animal" because this phrase lacks proper antecedent basis. While the claim previously refers to a "first animal" and a "second animal," the claim does not previously generally refer to "an animal."

Claims 15, 17, 19, 20 and 22 are indefinite and vague because the claims are drawn to methods for screening a cell for modulators, however, the claims recite only steps of assaying samples for RDGC GPCR phosphatase activity. The claims do not specifically analyze any particular cells and do not set forth the relationship between the samples and cells. Thereby, the claims do not recite a clear nexus between the preamble of the claims and the method steps of the claims and do not clarify how the analysis of samples results in the screening of a for modulators of RDGC GPCR phosphatase activity.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

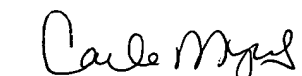
shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)-272-0735.

The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866)-217-9197 (toll-free).

Carla Myers
Art Unit 1634



CARLA J. MYERS
PRIMARY EXAMINER